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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,114	03/31/2006	Adam Bruce	9077-000010/US	7428

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EXAMINER	
GOUGH, TIFFANY MAUREEN	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
05/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,114	BRUCE ET AL.	
	Examiner	Art Unit	
	TIFFANY M. GOUGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed 1/16/2009 has been received and entered into the case. Claims 1-14 are pending. Claim 14 is withdrawn as being directed to a non-elected invention. All arguments and amendments have been considered. Claims 1-13 have been considered on the merits. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show detail as described in the specification. It is noted that applicant attempts to describe the drawings in their examples, while this is the incorrect arrangement (see Specification section), not only do the drawings fail to show detail described, the description is not complete. For example, on page 11 of applicant's specification applicant states that Fig. 8h-j illustrate the device without modification, one with one Ti-layer and one with two Ti-layers. It is not clear which figure is which. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be

removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: the arrangement of specification does follow the suggested guidelines, in particular there is no Brief Description of Drawings or Cross-References to Related Applications, such as priority documents.

Appropriate correction is required.

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites an implant as claimed in claim 1, wherein it is in the form of container. It is not clear what "it" is and it appears as if "a" is missing between "of" and "container."

Claim 9 recites "wherein the coating has a thickness from 5 nm." It appears as if applicant is/was attempting to claim a range. It is unclear what from 5nm encompasses.

The previous 112 2nd rejections of record have been withdrawn due to applicants claim amendments.

Response to Arguments

It is not clear as to why applicant has argued "semipermeable" in the response filed 1/16/2009. There were no rejections of record over "semipermeable."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Antananvich et al. (US 6372244 B1) in view of each of Okazaki (Adv. Engineering Materials, 2000, p. 278-281) and Wang et al. (US 2003/0153981 A1).

Antananvich teach an implant comprising a semipermeable barrier contaning a coating which allows or prevents diffusion of substances, material and molecules to the

opposite side of the barrier (abstract, col.19, lines 10-20, col. 20, lines 55-61, col.21, lines 27-28). The substances are produced in a human or animal body, i.e., cells (col. 19, lines 50-53, col. 21, lines 13-20).

Antananvich does not teach coating with a bioactive metal such as titanium, zirconium, tantalum or alloy.

Okazaki teach bioartifical implants which have been spray-coated with titanium. They teach that Ti, Zr and Ta exhibit excellent biocompatibility and are in the loose connective vascularized (vital) group for tissue reaction (p. 278, 1st paragraph, 2nd paragraph).

Wang et al (US 2003/0153981 A1) teach bioartifical implants which have been coated with metals such as titanium, alloy or tantalum (0032, 0084) by spraying (0090).

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to have coated the semipermeable membrane implant of Antananvich with a bioactive metal such as those disclosed by Wang and Okazaki because they are known in the art as being useful as coatings on implants as well as have excellent biocompatibility as is taught in Okazaki. Further, Antananvich clearly teaches a need for a biocompatible implant which allows nutrient diffusion further

disclosing the need for biocompatible materials to enclose the implant which are non-toxic and non-fibrogenic (col. 3, lines 20-col. 4, lines 1-35, col. 21, lines 14-20).

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to have coated with implant of Antanavich with a bioactive metal with a reasonable expectation for successfully providing a biocompatible implant because Okazaki clearly teaches the desirable characteristics needed by the Antananvich implant, i.e. excellent biocompatibility.

The above references do not teach the claimed form or coating thickness. However, it would be obvious to one of ordinary skill in the art to optimize such result effective variables as routine optimization.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brauker et al. (US 5782912) in view of Okazaki (Adv. Engineering Materials, 2000, p. 278-281) and Wang et al. (US 2003/0153981 A1).

Brauker teach an implant comprising a coated semipermeable barrier (col14., lines 15-17) which allows or prevents diffusion of substances, material and molecules to the opposite side of the barrier (col.3, lines 55-60, col. 4, lines 8-12, col, 6, lines 53-68, col. 7, lines 40-45). The substances are produced in a human or animal body, i.e., blood sugar (col. 13, lines 64-68). The implant further comprises a sensor element

enclosed by a membrane (col.5, lines 37-42, col. 13, lines 64-col. 14, lines 1-20). The sensor is disclosed as being a blood sugar detecting sensor element (col. 13, lines 64-col. 14, lines 1-20). Brauker also contemplate that the sensor can be coated with a material which circumvents the problem of foreign body occlusion and that materials such as metals could be used if manipulated to provide three dimensional structures (co. 14, lines 1-20).

Brauker does not teach coating with a bioactive metal such as titanium, zirconium, tantalum or alloy.

Okazaki teach bioartifical implants which have been spray-coated with titanium. They teach that Ti, Zr and Ta exhibit excellent biocompatibility and are in the loose connective vascularized (vital) group for tissue reaction (p. 278, 1st paragraph, 2nd paragraph).

Wang et al (US 2003/0153981 A1) teach bioartifical implants which have been coated with metals such as titanium, alloy or tantalum (0032, 0084) by spraying (0090).

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to have coated the semipermeable membrane implant of Brauker with a bioactive metal such as those disclosed by Wang and Okazaki because they are known in the art as being useful as coatings on implants as well as have excellent

biocompatibility as is taught in Okazaki. Further, Brauker clearly teaches a need for a biocompatible implant which decreases the foreign body response and allows for nutrient diffusion (col. 2, lines 30-50). They additionally suggest the use of materials such as metals if they could be manipulated into three dimensional structures. Okazaki and Wang clearly teach the use of the claimed metals as coatings on bioartifical implants with great success.

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to have coated with implant of Brauker with a bioactive metal with a reasonable expectation for successfully providing a biocompatible implant because Okazaki clearly teaches the desirable characteristics needed by the Brauker implant, i.e. excellent biocompatibility.

The above references do not teach the claimed form or coating thickness. However, it would be obvious to one of ordinary skill in the art to optimize such result effective variables as routine optimization.

Response to Arguments

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY M. GOUGH whose telephone number is (571)272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

/Tiffany M Gough/
Examiner, Art Unit 1657